REMARKS/ARGUMENTS

Status of the Claims

Claims 20-22, 28-29, 34-39, and 41-55 are pending in the subject application, among which claims 20, 36, and 46 are independent. Claims 1-19, 23-27, 30-33, and 40 have been previously cancelled without prejudice. No claim has been amended herein.

Reconsideration of the subject application in view of the following remarks is hereby respectfully requested.

Overview of the Office Action

Claims 20-22, 28-29, 34-39, 41-43, and 45-55 have been rejected under 35 U.S.C. §103(a) as unpatentable over US 6,761,719 (Justis) in view of US 5,290,289 to Sanders, in further review of US 6,592,605 to Lenker.

Claim 44 has been rejected under 35 U.S.C. §103(a) as unpatentable over Justis, in view of Sanders in further view of Lenker and further in view of US 6,296,643 (Hopf).

Patentability of the Claimed Invention

A. Independent Claim 20

Independent claim 20 recites a method for correcting spinal deformities by:

> providing a correction device comprising an elongated rod, the elongated rod having a pre-contoured shape of a normal degree of kyphosis and lordosis of at least a portion of the patient's spine, the elongated rod comprising a superelastic material having a transition temperature (A_f) within the range of human body temperature; and
>
> the correction force being generated by the superelastic material at the patient's body temperature and in an austenite phase of the superelastic material.

Based on the following detailed reasons, independent claim 20 is not obvious over the cited art.

(i)

The Office Action acknowledges that Justis does not teach its rod 302 comprising a superelastic material having a transition temperature (A_f) within the range of human body temperature, as is the claimed elongated rod (see page 4 of the Office Action). The Office Action then interprets the stent taught by Lenker as being formed of a superelastic material having a transition temperature (A_f) within the range of human body temperature (see page 5 of the Office Action) and alleges that it would be obvious to modify Justis's rod 302 based on the teachings of Lenker's stent (see page 6 of the Office Action).

Applicants disagree with the above interpretation of Lenker made by the Office Action because Lenker does not teach its stent being formed of <u>a superelastic material</u> having <u>a transition temperature (A_f) within the range of human body temperature</u> or otherwise remedies the deficiencies of Justis.

Lenker teaches a wire stent formed of shape memory nitinol or superelastic nitinol and having a trained shape as shown in Fig. 1 (see, col. 4, ll. 61-63 of Lenker). The stent will revert to the trained shape either through shape memory behavior at its chosen transition temperature or through superelastic behavior at body temperature (see col. 4, ll. 63-66).

In one example of Lenker cited by the Examiner, the stent can be made of a <u>shape memory alloy</u> with a transition temperature slightly <u>above</u> body temperature (see col. 4, ll. 46-51 of Lenker). As will be understood by one skilled in the art, such transition temperature referred to in the above example concerns a shape memory alloy material, rather than <u>a superelastic material</u> as recited in the claimed invention.

Moreover, the above Examiner-cited example of Lenker generally teaches that the transition temperature of the shape memory alloy is slightly <u>above</u> body temperature, without specifying whether such transition temperature is a starting temperature (A_s) or finish

temperature (A_f)." In a different example of Lenker, Lenker's shape memory alloy has a transition temperature A_f of about 30°C, plus or minus 5°C, so that a full expansion of the stent occurs above the normal room temperature and below the normal body temperature (see col. 4, ll. 50-53). In other words, Lenker teaches a transition temperature A_f <u>below</u> the normal body temperature, rather than <u>within the range</u> of human body temperature as is recited in the claimed invention. Therefore, the above-discussed example of Lenker does not teach what Justis lacks.

In the alternative example of Lenker cited by the Examiner, Lenker teaches that the stent can be superelastic at body temperature, in which the device will automatically revert to the memorized shape when inside the body (see col. 7, ll. 51-56 of Lenker). There is nevertheless no discussion in Lenker's alternative example about any transition temperature of such superelastic stent. Lenker teaches at most that its superelastic stent is superelastic at the body temperature, but not a transition temperature (A_f) at the body temperature. Lenker's teachings of a superelastic stent in no way suggest that the transition temperature (A_f) of such superelastic stent falls within the range of human body temperature.

As one skilled in the art will appreciate, the superelastic stent in Lenker may have a transition temperature (A_f) <u>below</u> the human body temperature range, while exhibiting superelastic behavior <u>at</u> the body temperature as is disclosed in Lenker. In such a case, Lenker's stent is no different from a conventional device, such as that taught in Drewry. Moreover, Lenker teaches that, if the transition temperature A_f is a degree or so <u>above</u> body temperature, hysteresis may be relied upon to ensure maintenance of superelastic properties when the material is cooled to body temperature (see col. 4, ll. 53-56 of Lenker). Therefore, such alternative example of Lenker does not teach that its superelastic stent has "a transition temperature (A_f) within the range of human body temperature," as is expressly recited in independent claim 20. Accordingly, such alternative example of Lenker does not teach what Justis lacks.

Sanders is cited in the Office Action against other claim features and does not remedy the deficiencies of the combination of Justis and Lenker.

Therefore, independent claim 20 patentably distinguishes over the cited art and is allowable for at least the above reasons.

(ii)

The Office Action also acknowledges that Justis does not teach generating the correction force by the superelastic material at the patient's body temperature and "in an austenite phase of the superelastic material" as recited in independent claim 20 (see page 5 of the Office Action). The Office Action then interprets the superelastic stent in Lenker as capable of generating a correction force in the austenite phase of the superelastic stent.

Applicants disagree with the above interpretation of Lenker made by the Office Action because Lenker is silent about an austenite phase of the superelastic stent or otherwise remedies the deficiencies of Justis. More specifically, the Examiner-cited portions of Lenker merely teach that the stent is superelastic at body temperature. There is no discussion concerning the different phases (i.e., austenite or martensitic phase) of the superelastic material of the stent, much less the phase in which the correction force is generated by the superelastic stent.

Without any specific teachings, one skilled in the art will appreciate that the superelastic stent of Lenker may generate a correction in a martensitic state of the superelastic stent, as does the spinal rod 302 in Justis (see, e.g., col. 13, ll. 5-8 of Justis). Therefore, Lenker does not teach "the correction force being generated by the superelastic material at the patient's body temperature and <u>in an austenite phase of the superelastic material</u>" as expressly recited in independent claim 20 or otherwise remedy the deficiencies of Justis.

Independent claim 20 thus patentably distinguishes over the cited art and is allowable for at least the above reasons.

In view of the foregoing, the claim rejection of independent claim 20 has been overcome.

B. Independent Claims 36 and 46

Independent claim 36 recites at least "the superelastic material having a transition temperature (A_f) within the range of human body temperature" and that "the supporting member generates the correction force at the patient's body temperature and in an austenite phase of the superelastic material." Independent claim 46 recites at least "generating a correction force at the recipient's body temperature and in an austenite phase of the superelastic material" and "the superelastic material having a transition temperature (A_f) within the range of human body temperature."

Similar to the above reasons submitted in connection with independent claim 20, independent claims 36 and 46 are also allowable.

C. Dependent Claims 21-22, 28-29, 34-35, 37-39, 41-45, and 47-55

Claims 21-22, 28-29, 34-35, 37-39, 41-45, and 47-55 depend, directly or indirectly, from allowable independent claim 1, 36, or 46 and are thus each allowable therewith.

In addition, these dependent claims include features which serve to even more clearly distinguish the claimed invention over the prior art of record.

Conclusion

Based on all of the above, the present application is now in proper condition for allowance. Prompt and favorable action to this effect and early passing of this application to issue are respectfully solicited.

Should the Examiner have any comments, questions, suggestions or objections, the Examiner is respectfully requested to telephone the undersigned in order to facilitate reaching a resolution of any outstanding issues.

No fees or charges are required at this time in connection with the subject application. If any fees or charges are required, they may be charged to the PTO Deposit Account No. 03-2412.

Respectfully submitted,
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